



The University of Texas System
Nine Universities. Six Health Institutions. Unlimited Possibilities.

Office of Health Affairs

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June 15, 2009

The University of Texas at Arlington

The University of Texas at Austin

The University of Texas at Brownsville

The University of Texas at Dallas

The University of Texas at El Paso

The University of Texas - Pan American

The University of Texas
of the Permian Basin

The University of Texas at San Antonio

The University of Texas at Tyler

Mr. Jerry Moore
NIH Regulations Officer
NIH, Office of Management Assessment
6011 Executive Boulevard
Suite 601, MSC 7669
Rockville, MD 20852-7669

*Reference: Responsibility of Applicants for Promoting Objectivity
in Research for Which Public Health Service Funding is Sought
and Responsible Prospective Contractors; Request for Comments,
May 8, 2009*

Dear Mr. Moore:

The University of Texas
Southwestern Medical Center at Dallas

The University of Texas
Medical Branch at Galveston

The University of Texas
Health Science Center at Houston

The University of Texas
Health Science Center at San Antonio

The University of Texas
M. D. Anderson Cancer Center

The University of Texas
Health Science Center at Tyler

The University of Texas System includes 15 campuses with overall research expenditures of \$2,169,200,000 in FY 2008. Health campuses accounted for \$1,412,800,000 of that total and receive approximately 70% of their support from federal sources, principally the National Institutes of Health (NIH).

Our institutions are members of both the Association of American Medical Colleges (AAMC) and the American Association of Universities (AAU).

The University of Texas System welcomes the opportunity to comment on the advanced notice of proposed rulemaking (ANPRM) and to join the AAMC and AAU in endorsing, without reservation, the principles that it articulates. We have also reviewed the response from AAU and AAMC transmitted to you as of June 10, 2009. The University of Texas System endorses all of the responses made by these two organizations in response to the request for comments.

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A number of the responses deserve special emphasis. The University of Texas System joins the associations in reiterating "their support for the principles articulated in ANPRM and affirm that the value of integrity in research is fundamental and does not differ in character depending on the nature of the research, with or without human subjects". In this regard, we believe that the threshold for disclosure of income to the public health service component to a level of \$5,000 income, \$5,000/0.1% ownership in a publicly traded company and a zero threshold for ownership interest in non-publicly companies are appropriate. Requiring disclosure below the \$5,000 income level will require a degree of administrative infrastructure, personnel costs, and time and effort which will substantially exceed the benefit from such a reporting level. In this regard, it is essential that income reported be aggregated over a twelve month reporting time and not be divided into small increments.

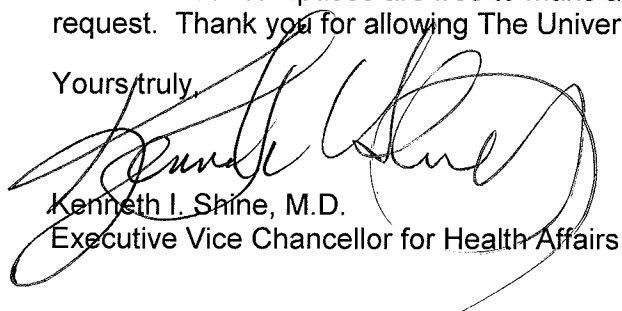
All of our institutions have far more than 50 employees. It is entirely appropriate that all of these institutions have an independent committee to review financial disclosures and that they report in the institution in a matter that is not conflicted by the short term financial interest of the investigator or the institution. Fifty employee thresholds would seem to be eminently reasonable.

The University of Texas System strongly agrees that there not be a NIH "prescribed standard for management plans". In view of the "varied facts and circumstances" encountered by our campuses, the reporting of such plans to the PHS would be entirely appropriate based on individual institutional circumstances. The University of Texas would reiterate the statement that "PHS, NIH and the Associations' institutions have taken great pains to establish that PHS funding is awarded to institutions, not to investigators, and that it is the institution, and not the investigator, that has the direct relationship with the awarding component and is comfortable for the expenditure of federal funds. That relationship would be distorted by imposing maximum limits on personal financial interests and create enormous problems in implementation, given the number of projects with both PHS and support from other funding sources."

As indicated in the AAMC/AAU letter, defining institutional conflict is a very challenging issue which requires substantial additional analysis and study. The University of Texas System has established a task force co-chaired by our General Counsel and Chief Compliance Officer to examine and rationalize conflict of interest policies across our 15 institutions. In the course of this analysis, we will be carefully studying the question of institutional conflict of interest, including its definition, application, interpretation, and oversight. In addition to strengthening our overall policies for conflict of interest as well as the application and implementation of those policies, the question of institutional conflict will be addressed. As a former investigator who has written about scientific integrity and other related matters I am committed to continued oversight and improvement of our efforts and the important areas of objectivity in research and conflict of interest.

Our individual campuses are free to make additional comments in response to your request. Thank you for allowing The University of Texas System to respond.

Yours truly,



Kenneth I. Shine, M.D.
Executive Vice Chancellor for Health Affairs